IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF NEW JERSEY

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	No. 19-md-2875-RBK Hon. Robert Kugler
This document relates to: *All Actions*	

MEDICAL MONITORING PLAINTIFFS' OPPOSITION TO DEFENDANTS' JOINT MOTION TO EXCLUDE THE OPINIONS OF EDWARD H. KAPLAN, M.D.

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I. INTRODUCTION

Dr. Edward H. Kaplan is an oncologist who (among other things) has treated *tens of thousands* of cancer patients, including patients diagnosed with each of the cancers at issue in this case. Dr. Kaplan has offered his expert opinion as to certain elements relevant to class treatment of medical monitoring: namely, the existence of a test/program that can mitigate the risks faced by the Medical Monitoring Class, demonstrating whether such a program exists turns on common evidence, as relevant for Rule 23.

In moving to strike Dr. Kaplan's opinions under *Daubert*, Defendants (a) attempt to re-litigate their failed arguments against general causation, although Dr. Kaplan is not a general causation expert, (b) ignore or mischaracterize Dr. Kaplan's actual experience and opinions, including as to risk and benefit, and (c) omit that Dr. Kaplan's methodology appropriately tracks his specific experience.[1] Dr. Kaplan is qualified and considered risk and benefit, thus his methodology is appropriate. The issues raised by the Defendants at best go to the weight of Dr. Kaplan's opinions, and not to their admissibility. Defendant's motion should be denied.

II. DR. KAPLAN'S QUALIFICATIONS AND OPINIONS

A. Dr. Kaplan's Qualifications

Dr. Kaplan is a board-certified medical oncologist who is familiar with cancer treatment based upon his training and experience. Ex. 2, Kaplan Rpt. 1. Dr. Kaplan received his Doctor of Medicine degree from Loyola-Stritch School of Medicine and completed his internship and residency training for internal medicine at Northwestern University Medical School. *Id.* While there, he received the Galter Fellowship and Bill Veek Fellowship, where he obtained additional training in hematology and oncology. Subsequently, Dr. Kaplan joined the faculty at Rush

[1] Defendants do not challenge the third prong of *Daubert*, that Dr. Kaplan's opinions are helpful to the finder of fact in deciding class certification under Rule 23.

University in Chicago, where he was later appointed Chairman of the Department of Hematology and Oncology at Rush North Shore Medical Center, and where he served as Assistant Professor of Medicine. *Id.*

Dr. Kaplan's experience in the field includes treatment of 20,000 to 30,000 patients over the course of his career, including some for whom he developed monitoring plans to address a patient's specific concerns about heightened risk of cancer. Ex. 3, Kaplan Dep. 96:19-21, 109:4-21. He has also authored over 60 research articles and presented at numerous scientific meetings across the country on cancer treatment and diagnosis. Ex. 2, Kaplan Rpt. 1. Dr. Kaplan's practice includes diagnosis and treatment of each of the types of cancer contemplated in his report.[2] *Id.* at 2.

B. Dr. Kaplan's Opinions

Dr. Kaplan provides his opinion to a reasonable degree of medical certainty that the medical monitoring program that he proposes will properly address the additional screening required due to ingestion of Defendants' contaminated valsartan at the level of the Lifetime Cumulative Threshold. *Id.* at 4.

The screening he recommends includes an annual physical and basic laboratory studies with an emphasis on those that may assist in detection of malignancies. *Id.* at 4. He also recommends, in light of the increased risk caused by contaminated valsartan, specialized testing that may be annual – i.e., Galleri, Cologuard, or low dose CT chest scans – or every five years – i.e., colonoscopy and upper endoscopy. *Id.*

The provision of these annual or periodic tests are based upon Dr. Kaplan's comparison of

[2] The only exception is that Dr. Kaplan does not treat patients with Acute Leukemia, as they generally require the resources of and receive treatment in a tertiary-care center. Ex. 3, Kaplan Dep. 26:21-27:13.

the relative risk[3] of a specific cancer caused by exposure to NDMA or NDEA at the LCT with established screening guidelines for populations with a similar relative risk of developing the same cancer. *Id.* 5-6. As set forth in more detail below, this approach presents a valid methodology.

III. ARGUMENT

Dr. Kaplan is qualified to design a medical monitoring plan for patients at risk of cancer and his proposed plan was reliably constructed.

A. Legal Standard

"Under the Federal Rules of Evidence, a trial judge acts as a 'gatekeeper' to ensure that 'any and all expert testimony or evidence is not only relevant, but also reliable.'" *Pineda v. Ford Motor Co.*, 520 F.3d 237, 243 (3d Cir. 2008) (citation omitted). Consistent with the "liberal thrust" of the federal rules of evidence, "Rule 702, which governs the admissibility of expert testimony, has a liberal policy of admissibility." *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 739 (3d Cir. 1994) (first quotation); *Pineda v. Ford Motor Co.*, 520 F.3d 237, 243 (3d Cir. 2008) (citation and quotation marks omitted) (second quotation). "Rule 702 has three major requirements: (1) the proffered witness must be an expert, i.e., must be qualified; (2) the expert must testify about matters requiring scientific, technical or specialized knowledge; and (3) the expert's testimony must assist the trier of fact." *Pineda v. Ford Motor Co.*, 520 F.3d 237, 244 (3d Cir. 2008). In this Circuit, "courts limit the *Daubert* inquiry to expert testimony offered to prove satisfaction of Rule 23's requirements." *In re Blood Reagents Antitrust Litig.*, 783 F.3d 183, 188 n.8 (3d Cir. 2015).

[3] "Relative Risk" means "the ratio of the risk of disease among those exposed to a risk factor to the risk among those not exposed." *Relative Risk*, Stedman's Medical Dictionary (2014); *see also id.* at *Odds Ratio* ("ratio of two odds, but as used in the analysis of data from a case control study, a simple calculation, also called the cross-products ratio, which yields an approximate value for the relative risk of the exposure that has been examined in a case control study").

B. Dr. Kaplan's Opinions Satisfy Rule 702 and the *Daubert* Standard

1. Dr. Kaplan is Qualified to Opine on Medical Monitoring

The first requirement of expert qualification under Rule 702 is "liberally construed" and satisfied if an expert "possesses specialized expertise." *Geiss v. Target Corp.*, No. 09–2208 RBK/KMW, 2013 WL 4675377, at *4 (D.N.J. Aug. 30, 2013) (quoting *Pineda.*, 520 F.3d at 244) (internal quotations omitted). Dr. Kaplan is a board-certified medical oncologist who has published peer-reviewed medical literature, is familiar with the literature and guidelines in the field of oncology, and has "designed screening programs for the patients [he] treats and frequently monitor[s] patients at high risk for cancer or cancer recurrence." Ex. 2, Kaplan Rpt. 1. He is qualified to opine on medical monitoring.

2. Dr. Kaplan's Testimony is Reliable under *Daubert*

The second Rule 702 requirement (also known as reliability) is taken to "mean[] that the expert's opinion must be based on the 'methods and procedures of science' rather than on 'subjective belief or unsupported speculation'" *In re Paoli R.R.*, 35 F.3d at 742 (citation omitted). While such "good grounds" for an expert's opinion are required, "[t]he grounds for the expert's opinion merely have to be good, they do not have to be perfect." *Id.* at 744. Good grounds may exist even if the court believes there "are better grounds for some alternative conclusion" or that "a scientist's methodology has some flaws such that if they had been corrected, the scientist would have reached a different result." *Id.*

To analyze reliability for scientific opinions, the Supreme Court has set out a list of non-exhaustive factors known as the *Daubert* factors:

> (1) whether a method consists of a testable hypothesis; (2) whether the method has been subject to peer review; (3) the known or potential rate of error; (4) the existence and maintenance of standards controlling the technique's operation; (5) whether the method is generally accepted; (6) the relationship of the technique

> to methods which have been established to be reliable; (7) the qualifications of the expert witness testifying based on the methodology; and (8) the non-judicial uses to which the method has been put.

Geiss, 2013 WL 4675377, at *4 (quoting *Elcock v. Kmart Corp.*, 233 F.3d 734, 745-47 (3d Cir. 2000)). Notably, reliability may be inferred from experience when the expert is applying the methods used from that experience. As the Supreme Court later held in *Kumho Tire*, the objective of *Daubert* "is to make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999).

Indeed, the *Daubert* test "may be more flexibly applied in cases where the expert testimony is based on experience." *In re Front Loading Washing Mach. Class Action Litig.*, No. 08-51(FSH), 2013 WL 3466821, at *2 (D.N.J. July 10, 2013) (expert's experience in the field designing washing machines qualified him to opine on washing machine design flaw). Moreover, in the case of experience-based opinions, the fact that an expert has been determined to be qualified weighs in favor of the reliability of her report. *Altieri v. State Farm Fire & Cas. Co.*, No. 09-2342, 2011 WL 1883054, at *3-4 (E.D. Pa. May 17, 2011).

Dr. Kaplan has opined that he would prescribe the screening regimen he describes in his report based upon the relative risk of cancer caused by ingestion of NDMA or NDEA at the Lifetime Cumulative Threshold (LCT). Ex. 2, Kaplan Rpt. 1-2. Because he has seen tens of thousands of patients and "frequently monitor[s] patients at high risk for cancer or cancer recurrence" the methods he employs are well-established in the practice of medicine both in general and based on his specific experience. *Id.* at 1. For example, the Annual History/Physical and Laboratory Studies are the same that he or any other medical doctor would provide to a patient

who was in his office due to concern over an increased risk of cancer. *Id.* at 4; Ex. 3, Kaplan Dep. 45:8-20. Dr. Kaplan also states that he would prescribe Galleri to his patients because it provides the unique benefit of detecting certain cancers early, *id.* at 92:9-22, and Galleri could "could detect cancer across multiple cancer types and predict cancer with high accuracy." Ex. 2, Kaplan Rpt. 4. Indeed, he cites a study of Galleri in his report that found that the "specificity for cancer signal detection" was 99.5%. *Id.* Defendants prefer not to use Galleri (which is just one aspect of the program) due to what they consider lack of sensitivity. Ex. 1, Defs.' Br. 21; Ex. 6, Teitelbaum Dep. 182:3-9 (agreeing that her "primary concern" with Galleri was the false negative rate, but acknowledged that "the good news is it didn't seem to have false positives").

The parties' disagreement over the suitability of using this aspect of the proposed program is really a classic battle of the experts, which goes to weight, not admissibility. *See also, e.g., In re Johnson & Johnson Talcum Powder Prod. Mktg., Sales Pracs. & Prod. Litig.*, 509 F. Supp. 3d 116, 184 (D.N.J. 2020) ("[T]he fact that experts may disagree as to how to interpret the relevant studies at issue does not indicate one expert is more reliable than the other. Moreover, to the extent there are competing studies relied upon by the parties' experts, a weighing of those studies is reserved for the factfinder at trial."). Support for these screening methods is well-established and Defendants' arguments on this point, as with the others, goes at most to the weight of Dr. Kaplan's opinions.

The other screenings Dr. Kaplan recommends also comport with existing national guidelines if compared with an equivalent risk factor or exposure. Thus, adheres to standards and generally accepted methods that have been established to be reliable. For example, Dr. Kaplan applied a conservative approach (as he did throughout) and finds comparable the relative risk of colorectal cancer of a person exposed to NDMA or NDEA (.99-2.12) with that of a person with a

first degree relative with the same cancer (1.8-2.7). Ex. 2, Kaplan Rpt. 5. Because the relative risk of these populations is comparable, Dr. Kaplan may reliably recommend an equivalent screening schedule of a colonoscopy every five years per Multi-Society Task Force of Colorectal Cancer (MSTF) guidelines. *Id.* at 6. Dr. Kaplan's other recommendations are based on similar comparisons to national guidelines, so are similarly related to methods that are considered reliable. *See id.* (relative risk of gastric (1.32-1.34) and esophageal cancer (1.27) is "within the range of risk for which endoscopic surveillance is considered"); *id.* at 6 (relative risk of lung cancer for NDMA or NDEA exposed population (1.05-3.3) justified recommendation for annual CT low-dose CT scan, the "same frequency recommended by the USPSTF for long-time smokers").

Defendants' real concern is that Dr. Kaplan proposes a plan that is different from the one that would be proposed to the asymptomatic population *without* known risk factors. But that ignores the actual population here, to which Dr. Kaplan rightly tailored his plan.

3. Dr. Kaplan's Testimony is Relevant

The third requirement of Rule 702, known as relevance, is satisfied "if an opinion fits a particular case (and thus helps the trier of fact)" – i.e., there must be a "connection between the scientific research or test result to be presented and particular disputed factual issues in the case." *Geiss*, 2013 WL 4675377, at *5 (internal quotation marks omitted). Dr. Kaplan's opinions recommending a medical monitoring program to screen for and detect cancer at a treatable stage are essentially co-extensive with three of the elements of medical monitoring. *Compare Gates v. Rohm & Haas Co.*, 655 F.3d 255, 265 (3d Cir. 2011) (describing last three elements as (1) "a monitoring procedure exists that makes the early detection of the disease possible;" (2) "the prescribed monitoring regime is different from that normally recommended in the absence of the exposure;" and (3) "the prescribed monitoring regime is reasonably necessary according to contemporary scientific principles."), *with* Ex. 2, Kaplan Rpt. 3-4 ("It is my opinion to a reasonable

degree of medical certainty that there exist diagnostic tests that can mitigate the risks of developing cancer faced by the class of people because of their exposure to contaminated valsartan (who have a level of exposure greater than or equal to the LCT), and that this program is different than the one that would have been prescribed in the absence of that particular exposure and increased risk. Furthermore, it is my opinion that this monitoring is both reasonable and necessary."). Relevance is unchallenged and established.

C. Defendants' Arguments Fail

Defendants' arguments largely eschew the proper Rule 702 and *Daubert* analysis and instead misstate or ignore the legal standard for qualification and reliability by creating an artificially high bar for admissibility. Dr. Kaplan was not tasked with establishing causation or deciding the ultimate merits of the entire claim.

1. Defendants' Challenges to Dr. Kaplan's Qualifications to Opine on Medical Monitoring are Unfounded.

Defendants argue that Dr. Kaplan is not qualified to opine on a medical monitoring program for persons exposed to NDMA or NDEA because he is a practicing oncologist who treats people with cancer. Ex. 1, Defs.' Br. 20-21. Defendants argue that this demonstrates Dr. Kaplan lacks the "specific knowledge" to opine on medical monitoring because of the general proposition that "[w]hile the background, education, and training may provide an expert with general knowledge to testify about general matters, more specific knowledge is required to support more specific opinions." *Calhoun v. Yamaha Motor Corp., U.S.A.*, 350 F.3d 316, 322-23 (3d Cir. 2003).[4] But it is obviously apparent from his education, publications, and extensive practice experience,

[4] Defendants fail to mention that the expert in *Calhoun* was a psychologist who wished to make the specific claim that the "the proper age for jet ski use is sixteen" based on his "general knowledge in the fields of psychology and human factors engineering." *Id.* at 323. Aside from being factually dissimilar as a failure to warn case regarding a motor vehicle, unlike the study of psychology and jet skis, the study of oncology is directly tied to cancer development.

Dr. Kaplan has specific expertise and knowledge in the areas of cancer diagnosis, surveillance, and treatment which is directly tied to cancer screening and medical monitoring. *See* Ex. 2, Kaplan Rpt. 1. In the course of treating tens of thousands of patients with cancer, Dr. Kaplan has also frequently devised monitoring programs for persons at high risk of certain forms of cancer, such as the BRCA gene, Lynch Syndrome, or Barrett's esophagus. Ex. 3, Kaplan Dep. 60:17-62:5, 108:23-109:21; *see also* Ex. 2, Kaplan Rpt. 1 ("I treat and frequently monitor patients at high risk for cancer or cancer recurrence."). Dr. Kaplan is plainly qualified to apply his "specific" experiences in devising cancer screening programs for his at-risk and undiagnosed patients. Ex. 3, Kaplan Dep. 60:17-62:5, 108:23-109:21; *Zink v. McClung*, No. 5:14CV25, 2014 WL 12596538, at *5 (N.D.W. Va. Nov. 14, 2014) (pathologist was qualified to opine on a plaintiff's cause of death "through his specialized knowledge and experience"); *cf. In re Whirlpool Corp. Front-Loading Washer Prod. Liab. Litig.*, 45 F. Supp. 3d 724, 736 (N.D. Ohio 2014) (expert qualified to opine on design defect based on "his own experience in washer design", though he "conducted no scientific testing in the strict sense").

The other cases Defendants cite that pertain to medical monitoring are easily distinguishable. The *Allgood* case involved the exclusion of a toxicologists opinions regarding a medical monitoring program, where he was "not and ha[d] never been licensed to practice medicine" and was "not board certified in any medical field"; he therefore was "not eligible to diagnose or to prescribe treatments or any diagnostic testing that [were a] part of his proposed program."*Allgood v. Gen. Motors Corp.*, No. 102CV1077DFHTAB, 2006 WL 2669337, at *29 (S.D. Ind. Sept. 18, 2006). Dr. Kaplan is a board-certified medical oncologist and therefore has the attributes to devise a treatment plan. The *Arias* case is also distinguishable because the court excluded the opinion because "plaintiffs offer[ed] no further explanation as to how [their expert's]

education qualifie[d] him to offer [medical monitoring] testimony or how his experience caused him to reach his conclusion" in their opposition brief. *Arias v. DynCorp*, 928 F. Supp. 2d 10, 25 (D.D.C. 2013). In addition to the patently obvious connection between Dr. Kaplan's education and study of cancer metastasis and screening for cancer, the discussion herein goes far beyond and could not be reasonably referred to as "[c]onclusory statements that an expert is qualified because of his education or experience." *Id.*

Finally, this challenge to Dr. Kaplan's qualifications is revealed to be even more problematic because Dr. Teitelbaum (the expert Defendants proffer to challenge Dr. Kaplan's opinions) is likewise a treating oncologist who by her own admission has not monitored patients without a cancer diagnosis since 2006.[5] Ex. 5, Teitelbaum Rpt. 1-2; Ex. 6, Teitelbaum Dep. 234:5-20. Defendants also proffer Dr. Chan as an expert to challenge Dr. Kaplan's opinions despite the fact that: (1) Dr. Chan is a general practitioner rather than an oncologist; (2) he only treats patients between four and eight weeks *each year*; (3) he does not follow "cancer patients long-term"; and (4) his academic work does not concern cancer diagnosis. Ex. 7, Chan Rpt. 16-18, 94; Ex. 8, Chan Dep. 46:2-6 (describing self as a "hospitalist" who "by definition is a general internist who does not have a subspecialty"), 46:13-47:19 (stating that a doctor like himself sees patients between four and eight weeks a year), 61:15-23, 92:1-3 (no research specific to cancer screening). This comparison highlights the weakness of Defendants' experts and the objectively superior experiential qualifications of Dr. Kaplan.

[5] Dr. Kaplan also treats all of the cancers contained in Plaintiffs' medical monitoring program; Dr. Teitlbaum has released marketing videos stating that she *only* treats gastrointestinal tract cancers. *See* Ex. 6, Teitelbaum Dep. 50:6-58:10.

2. Dr. Kaplan Was in No Way Required to Perform His Own Analysis of Causation. The Work of Other Experts Does Not Impact the Reliability of His Opinions on Medical Monitoring.

Defendants argue that Dr. Kaplan's opinion lacks a reliable basis because he did not independently study whether Plaintiff's Lifetime Cumulative Threshold (LCT) was accurate and instead relied upon the work of other experts. Defs.' Br. 11. Effectively, Defendants are asking this Court to require Plaintiffs to present an expert who can wear all hats by providing independent proof of causation and also possess the years of experience with cancer screening and treatment required to establish a medical monitoring remedy.

This is not how expert testimony works and there is no such requirement; experts are qualified to opine on issues specific to a particular field of experience or education, they are not required to individually prove every element of the case in one go and especially in a case as complex as this. It is appropriate for Plaintiffs to proffer multiple experts. *See, e.g., Chen-Oster v. Goldman, Sachs & Co.*, 114 F. Supp. 3d 110, 125 (S.D.N.Y. 2015), *objections overruled*, 325 F.R.D. 55 (S.D.N.Y. 2018) (allowing testimony by industrial/organizational psychologist who opined on infirmities with challenged employment systems, overruling the defendant's argument that the expert had failed to opine on causation between the systems and harm to women; "it is not necessary for each expert to provide evidence establishing every element of a party's case, and the plaintiffs have proffered [a statistician's] analyses in order to prove causation."). "While experts may not simply 'parrot' ideas of other experts, they 'are permitted to rely on materials used by other experts in developing their own opinions.'" *Leese v. Lockheed Martin Corp.*, 6 F. Supp. 3d 546, 553 (D.N.J. 2014) (quoted in *Edmond v. Plainfield Bd. of Educ.*, No. 11-CV-2805 KM/JBC, 2018 WL 4380991, at *6 (D.N.J. Sept. 13, 2018)).

In this case, Dr. Kaplan, who is a practicing oncologist, reviewed the reports of Plaintiffs' other experts and properly relied on the facts and data that Dr. Madigan, who is a drug safety

statistician, for his assumption that the exposure at the level prescribed in the LCT was actually sufficient to create the relative risk necessary to justify screening beyond that which is generally recommended. Ex. 2, Kaplan Rpt. 5-6 (citing Ex. 4, Madigan Rpt. 5); Ex. 3, Kaplan Dep. 65:7-13 ("What medically makes sense is based on my . . . development of what I consider to be appropriate screening for the patients that are at risk . . . based on my understanding of the diseases and my review of the literature as outlined."). This was an appropriate division of labor between the experts that emphasized their expertise in their respective fields.

An analogous case involved exposure to toxic rain. *Patrick v. FirstEnergy Generation Corp.*, No. CIV.A. 08-1025, 2014 WL 1318017, at *1 (W.D. Pa. Mar. 31, 2014). There, the court rejected defendants' attacks on the reliability of plaintiffs' expert opinion recommending an additional health assessment study in light of defendants' conduct because defendants failed to appreciate that the scope of the expert's testimony did not extend to causation. *Id.* at *4-5. As the *Patrick* court explained, "Plaintiffs are not offering [their expert] Smith to opine about causation (which would be elements one through three discussed above); Smith is opining about whether a health assessment or health effects study should be ordered. In light of this limitation, the court concludes that Smith's failure to definitively link [defendant] to any harm to plaintiffs does not render his opinion about the necessity of a health assessment or health effects study inadmissible." *Id.* at *5 (citations omitted)). The same is true here; though Dr. Kaplan has read and understands the basis for causation, his opinions relate to whether enhanced medical monitoring is necessary and appropriate, not whether NDMA or NDEA causes cancer. Ex. 2, Kaplan Rpt. 2-3, 5-6.

Defendants' cite to several quotes from Dr. Kaplan's deposition where they try to draw him into providing irrelevant opinions outside the scope of his work about whether NDMA or NDEA may cause cancer or whether exposure can be calculated. Ex. 1, Defs.' Br. 11-15. This

strawman argument completely sidesteps Dr. Kaplan's role in this litigation: he is not an expert on causation, he is a medical monitoring expert who is qualified to opine on what screenings are appropriate with the assumption that a cancer-causing exposure has taken place. Ex. 2, Kaplan Rpt. 2; *see Sullivan v. Saint-Gobain Performance Plastics Corp.*, No. 5:16-CV-125, 2019 WL 12323322, at *12 (D. Vt. July 15, 2019) ("In considering the Daubert issues, the court assumes for the sake of argument that medical monitoring is a remedy available under Vermont law. The evidentiary issue is whether these witnesses have provided admissible opinions about whether the remedy should be ordered in this case and in what form."). Defendants already tried and failed to exclude the opinions of Plaintiffs' experts on causation and now seek to recast Dr. Kaplan's opinions as general causation to take a second bite at the apple. *See* Daubert Order 1 (ECF No. 1974); Daubert Order 2 (ECF No. 1958). This Court should decline to hear renewed challenges to general causation that already have been through this inappropriate vehicle.

The remaining cases Defendants' cite do not support their position. For example, in *Edmond*, while the court acknowledged that parroting of other expert opinions was not permissible, it ultimately found that although the expert in question made "several references" to another expert's opinion, it did not "parrot [the other expert's] conclusions or diagnosis." *Edmond v. Plainfield Bd. of Educ.*, No. 11-CV-2805 KM/JBC, 2018 WL 4380991, at *6 (D.N.J. Sept. 13, 2018). The same is true here, while Dr. Kaplan does reference other expert's opinions, he has not parroted them but rather opines on wholly separate remedy issues.

Similarly, in *Hunt* the court excluded the expert's opinion because, unlike here, "the majority of his report was copied verbatim from other reports" and he "conceded in his deposition that he did not read most of the material cited in the opinions nor verify the data referenced therein." *Hunt v. McNeil Consumer Healthcare*, 297 F.R.D. 268, 275 (E.D. La. 2014). Dr. Kaplan

wrote his own report and clearly indicated which expert reports he reviewed and which assumptions he was making based upon those reports.[6] Ex. 2, Kaplan Rpt. 2. Defendants' citation to *In re TMI* is also unavailing for similar reasons; in that case the expert relied upon radioactive contamination in trees to prove human contamination that he admitted was never actually used in the field and then "ignored his own stated principles of risk assessment" in endorsing the other experts' underlying opinions. *In re TMI Litig.*, 193 F.3d 613, 715 (3d Cir. 1999), *amended*, 199 F.3d 158 (3d Cir. 2000). Dr. Kaplan never stated that the methodology he used to arrive at his conclusions was anything but information he would rely upon in his own practice.[7]

Defendants also cite to *Allgood* to claim that Dr. Kaplan should have reviewed a press release from the FDA and a determination by the European Medicines Agency in forming his opinion. Ex. 1, Defs.' Br. 15. As discussed above, this challenge fails fundamentally—and veers totally outside of Daubert, and the specific question for the Court here. If this were at all relevant for Dr. Kaplan, which it is not, it would simply go to weight. That is, even if Dr. Kaplan were opining on causation, which he is not, and even if the Court had not already ruled on expert challenges for that phase of the case, which it has, the relevance of these materials, if any, is an

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[6] *See also* Ex. 3, Kaplan Dep. 78:17-79:4 ("[M]y understanding of [Plaintiffs'] experts' evaluation is that the amount of NDMA found in the vast majority of people from indigenous or naturally occurring substances is quite lower than . . . the toxic levels that were found in the product that we're discussing, so . . . it's unlikely that somebody would have just from those other things enough exposure, enough levels to render them at significant risk.").

[7] By citing these cases, Defendants also appear to make a half-formed argument under Federal Rule of Evidence 703. Ex. 1, Defs.' Br. 11. But "[t]he proper inquiry [under Rule 703] is not what the court deems reliable, but what experts in the relevant discipline deem it to be." *In re Paoli R.R.*, 35 F.3d at 747. Defendants have not argued that any of the data in the expert reports that Dr. Kaplan relied upon are not the kinds of data that an expert in the field of cancer screening or treatment would rely upon. *See* Ex. 1, Defs.' Br. 11-15 (absence); Ex. 2, Kaplan Rpt. 2 (listing experts relied upon). A "moving party may not raise new issues and present new factual materials in a reply brief that it should have raised in its initial brief." *In re BlackRock Mut. Funds Advisory Fee Litig.*, 327 F. Supp. 3d 690, 736 (D.N.J. 2018), *aff'd*, 816 F. App'x 637 (3d Cir. 2020). Thus Defendants' have waived any argument to that effect under Rule 703.

evidentiary weight issue. Dr. Kaplan's report is based upon the well-founded and permissible assumption that the LCT caused an increased risk of cancer. He did not need to weigh every source of information that might touch on the expert opinion he relied upon. *See In re Whirlpool Corp. Front-Loading Washer Prod. Liab. Litig.*, 45 F. Supp. 3d 724, 735 (N.D. Ohio 2014) ("Regardless of whether Wilson explicitly cited [an ASSE industry standard document] in his Report, the general design principle (the 'need to self-clean') that Wilson articulates is consistent with the ASSE standard" and therefore "enjoyed sufficient 'general acceptance' within the 'relevant scientific community,' as required by *Daubert*."). Second, the sources that the *Allgood* court found that the excluded expert should have considered in opining on medical monitoring were "guidelines or protocols of either the American Medical Association, the Centers for Disease Control, or USPSTF." *Allgood v. Gen. Motors Corp.*, No. 102CV1077DFHTAB, 2006 WL 2669337, at *31 (S.D. Ind. Sept. 18, 2006). Dr. Kaplan explicitly considers similar "national guidelines" in formulating his opinion – e.g., National Cancer Institute (NCI), United States Preventive Services Taskforce (USPSTF). Ex. 2, Kaplan Rpt. 5-6. Third, the FDA press release cited by Defendants states that patients should not stop taking contaminated products because they will put themselves at risk of heart failure; continued exposure to a carcinogen versus a present risk of heart failure is a Hobson's choice.[8] The Court is well aware that this recommendation was focused on the short term, so patients would not abruptly cease their blood pressure medication and die, but rather switch to a new safe medication in consult with their doctors. And while the European Medicines Agency statement may have some relevance as a government source, "the failure to consider certain potentially relevant data goes to the weight of the testimony" and not its

[8] Ex. 9, Statement on the Agency's Ongoing Efforts to Resolve Safety Issue with ARB Medications, U.S. Food & Drug Admin (Aug. 28, 2019), https://www.fda.gov/news-events/press-announcements/statement-agencys-ongoing-efforts-resolve-safety-issue-arb-medications.

admissibility. *In re TMI Litig. Cases Consol. II*, 922 F. Supp. 1038, 1043–44 (M.D. Pa. 1996). Dr. Kaplan has reviewed appropriate government publications and adequately considered the opinions he relied on, and his reliability cannot be questioned on this basis.

3. Defendants' Balance of Risk Argument Lacks Legal Basis; Additionally, Dr. Kaplan Weighed the Risks of His Monitoring Program Against the Risk of Cancer Caused By Defendants.

Defendants argue that Dr. Kaplan's opinions are unreliable because, they assert, he failed to account for the risks presented by the medical monitoring program. Ex. 1, Defs.' Br. 15-16. As shown below, this is false: Dr. Kaplan factored in risk. Defendants further claim that because Dr. Kaplan has acknowledged that certain screenings may carry some risk, that these must outweigh the benefits of the screening. *Id.* at 17. Defendants' own extreme position, that there should be no screening here, no matter how effective, simply highlights that risk/benefit is a battle-of-the-experts issue. *But see* Ex. 6, Teitelbaum Dep. 74:14-18 ("if I could, [I would] find every cancer early and treat curatively"); 117:22-24 ("Cancer screening is designed to find cancers earlier when they're more amenable to treatment.").

As an initial matter, Defendants' argument is yet another improper attempt to revisit causation in an inappropriate context. Defendants and their experts may address their argument regarding the relative risk of cancer their product caused at the merits stage to the finder of fact, not in a *Daubert* motion. *See Walker v. Gordon*, 46 F. App'x 691, 695-96 (3d Cir. 2002) ("An expert is . . . permitted to base his opinion on a particular version of disputed facts and the weight to be accorded to that opinion is for the jury." (citing *Stecyk v. Bell Helicopter Textron, Inc.*, 295 F.3d 408, 414 (3d Cir. 2002) ("Rule 705, together with Rule 703, places the burden of exploring the facts and assumptions underlying the testimony of an expert witness on opposing counsel during cross-examination.")). Dr. Kaplan specifically opines on whether monitoring is justified with the assumption that the LCT is sufficient to show increased risk of cancer, he is not called

upon to opine on any risk-benefit calculation that presupposes that Defendants' products were not harmful. Ex. 2, Kaplan Rpt. 2.

Second, Dr. Kaplan addressed risk/benefit in multiple respects. Ex. 2, Kaplan Rpt. 3-6. For each of the tests that Defendants allege are overly risky,[9] Dr. Kaplan first compared the relative risk of a population exposed to NDMA or NDEA as determined by Plaintiffs' experts with the relative risks that justify screening under cancer screening guidelines. *See* Ex. 2, Kaplan Rpt. 5-6; *see also* Ex. 4, Madigan Rpt. 9. In making these comparisons Dr. Kaplan is recommending only those screening tests that are already established and widely-accepted screening practices for populations with a similar relative risk of developing the same cancer.[10] Dr. Kaplan therefore has weighed the risk associated with these tests.

With respect to periodic tests that supposedly carry more risk, Dr. Kaplan clearly testified that they were "within the limits of accepted risk for general population." Ex. 3, Kaplan Dep. 73:11-15. For example, according to Defendants' expert Dr. Teitelbaum, the "gold standard" for "well[-]established screening tests for asymptomatic patients" is colonoscopy and they are recommended "every 10 years for standard risk patient and every 5 years for screening in moderately high risk patients." Ex. 5, Teitelbaum Rpt. 6, 22. If the degree of risk presented by colonoscopy is appropriate even for populations who have *no risk* factors at all, Ex. 5, Teitelbaum Rpt. 22, then the test should be presumed to be appropriate for the population exposed to a

[9] Many of procedures that Dr. Kaplan recommends are non-invasive and carry very little risk – i.e. a normal physical exam and blood tests, the Galleri multi-cancer early detection blood test (MCED), and Cologuard is a fecal test for colon cancer. *Id.* at 4. Defendants failed to mention these tests at all in their motion while lumping them in with more invasive tests, this Court should presume Defendants have no issue with physical consequences of these tests.

[10] *See supra* section B.2 for a discussion of Dr. Kaplan's relative risk analysis.

carcinogen that increases their likelihood of cancer – even if testing occurs twice as often.[11] Ex. 2, Kaplan Rpt. 5.

Next, Defendants' vague and unsupported allusions to other risks should not be credited as they are based solely upon the *ipse dixit*[12] statements of their expert, Dr. Teitelbaum. Ex. 1, Defs.' Br. 17. Defendants have cited to no evidence that the radiation caused by low-dose CT scans is unreasonable when compared with the risk of cancer brought on by Defendants' contaminated valsartan. *Id.* (citing Ex. 5, Teitelbaum Rpt. 5, 6, 18 (fails to compare risk of allegedly unnecessary radiation with risk of cancer caused by contaminated valsartan)). By contrast, Dr. Kaplan has considered the "high risk for lung cancer that justifies the risks of screening in national guidelines" that is similar to the relative risk caused by exposure to contaminated valsartan and found it sufficient to outweigh the "risks associated with low dose CT scanning of the lungs" in light of "the lack of other viable screening modalities and the high risk for lung cancer that justifies the risks of screening in national guidelines." Ex. 2, Kaplan Rpt. 6. Additionally, the alleged psychological risks of testing that Dr. Teitelbaum cites in her report were based on an apparently one-sided review of the literature, which itself is sparse. *See* Ex. 5, Teitelbaum Rpt. 16-17; Ex. 6, Teitelbaum Dep. 137:2-19 (discussing literature on anxiety caused by testing), 253:24-255:12 (acknowledging article cited was premised on a hypothetical), 136-140 (discussing her review of the literature), 220-227 (discussing peer-reviewed article directly on point she had not looked for that confirmed the anxiety of testing more manageable than the greater anxiety of not knowing).

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[11] Relatedly, Defendants cannot seriously claim that the risk of perforation, which occurs in .016% to .8% of colonoscopies and is highly dependent upon the skill of the practitioner, is a significant risk that goes beyond the need for early detection of malignancy. Ex. 1, Defs.' Br. 17; Ex. 5, Teitelbaum Rpt. 23.

[12] *Oddi v. Ford Motor Co.*, 234 F.3d 136, 158 (3d Cir. 2000) ("An expert's opinion must be based on the methods and procedures of science rather than on subjective belief or unsupported speculation." (citation and quotation marks omitted)).

Further, and notably, by Dr. Teitelbaum's admission, much of the anxiety surrounding testing is traceable to "tremendous economic toxicity from all of the tests," a concern that would be forestalled by institution of a class-wide medical monitoring program paid for by Defendants. *See* Ex. 6, Teitelbaum Dep. 189:11-12, 190:13-22. None of Defendant's arguments regarding risk present any significant issue as to the reliability of Dr. Kaplan's opinions, especially when these risk are compared with the risk of developing late-stage cancer that is more difficult to treat.

Third, in claiming that Dr. Kaplan is not reliable, Defendants rely almost exclusively on *In re Paoli R.R. Yard PCB Litig.*, No. 86-2229, 2000 WL 274262, at *8 (E.D. Pa. Mar. 7, 2000), a completely inapposite case. The proposed expert there had "dubious" expertise– she no longer saw patients, and had admitting privileges at no hospital.[13] The proposed expert also had no bases to support the screening offered, suggested tests with "no known medical benefit in treatment of any condition," failed to consider or analyze the "accuracy of the tests," and failed to "consider[] the prevalence of the target diseases." *Id.*

By contrast, the screenings that Dr. Kaplan proposes are either virtually harmless or widely adopted by screening guidelines covering patients at a similar level of relative risk as the class, which inheres a great degree of confidence in their effectiveness and accuracy in identifying treatable cancer. Ex. 2, Kaplan Rpt. 2 ("I certify that the monitoring proposals detailed above have the potential to significantly improve the outcomes of patients that may be destined to develop malignancies due to their exposures and do not pose any significant risks or negative consequences."). Additionally, Dr. Kaplan has considered the prevalence of the target cancers through his reliance upon the relative risk calculations performed by Plaintiffs' experts. The situation in *In re Paoli R.R.* is not applicable to the facts here.

[13] *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 753 (3d Cir. 1994).

Even if the case had any relevance here, Defendants misapply its dicta in any event. There is no obligation arising out of this case or any other for a medical monitoring expert to use any magic words or engage in a rote recitation exercise: what is required is they are qualified and use reliable methods to devise a program. *See In re Paoli R.R.*, 35 F.3d 717, 750 (3d Cir. 1994) ("The expert need not express his opinion in precisely the same language we use to enunciate the legal standard." (quoting *Cohen v. Albert Einstein Medical Ctr.*, 592 A.2d 720, 724 (1991))). The Court in *Paoli* noted in passing that "like any medical intervention, the physician must first establish that the probable usefulness of those tests outweighs the attendant risks prior to subjecting a healthy person to screening tests. Such a risk/benefit analysis determines whether a screening test for an asymptomatic patient is justified." *In re Paoli R.R.*, 2000 WL 274262, at *8 (E.D. Pa. Mar. 7, 2000). This Court is not required to give this statement in an unpublished district court decision any deference as a statement of what an expert must recite, especially in light of the fact that the statement has never been cited for the same proposition in over two decades.

IV. CONCLUSION

For the reasons set forth above, it is submitted that this Court can and should deny Defendant's motion, and permit and consider Dr. Kaplan's opinions on whether a medical monitoring class or classes should be certified.

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Respectfully submitted,

By: */s/ Nicholas Migliaccio*
Nicholas Migliaccio
nmigliaccio@classlawdc.com
Jason Rathod
jrathod@classlawdc.com
MIGLIACCIO & RATHOD LLP
412 H Street NE, Suite 302
Washington, DC 20002
Telephone: (202) 470-3520
Facsimile: (202) 800-2730

Proposed Medical Monitoring Co-Lead Class Counsel

By: */s/ Rachel Geman*
Rachel Geman
rgeman@lchb.com
LIEFF CABRASER HEIMANN & BERNSTEIN, LLP
250 Hudson Street, 8th Floor
New York, NY 10013-1413
Telephone: (212) 355-9500
Facsimile: (212) 355-9592

Proposed Medical Monitoring Co-Lead Class Counsel

By: */s/ Daniel Nigh*
Daniel Nigh
LEVIN, PAPANTONIO, THOMAS, MITCHELL, RAFFERTY & PROCTOR, P.A.
316 South Baylen Street
Pensacola, FL 32502
Phone: (850) 435-7013
dnigh@levinlaw.com

By: */s/ Adam Slater*
Adam Slater
MAZIE, SLATER, KATZ & FREEMAN, LLC
103 Eisenhower Pkwy, 2nd Flr.
Roseland, NJ 07068
Phone (973) 228-9898
aslater@mazieslater.com

By: */s/ Ruben Honik*
Ruben Honik
HONIK LLC
1515 Market Street, Ste. 1100
Philadelphia, PA 19102
Phone (267) 435-1300
ruben@honiklaw.com

By: */s/ Conlee S. Whiteley*
Conlee S. Whiteley
KANNER & WHITELEY, LLC
701 Camp Street
New Orleans, LA 70130
Phone: (504)-524-5777
c.whiteley@kanner-law.com

MDL Plaintiffs' Co-Lead Counsel, on behalf of the Plaintiffs' Executive Committee and all Plaintiffs

CERTIFICATE OF SERVICE

I hereby certify that on this 25th day of May, 2022, I caused a true and correct copy of the foregoing to be filed and served upon all counsel of record by operation of the Court's CM/ECF system. In addition, I certify that unredacted versions of the foregoing will be served contemporaneously upon liaison counsel for Defendants as well as the Court.

/s/ *Rachel Geman*
Rachel Geman